

**Remarks/Arguments**

The present amendment amends 12, 31, 58-68, 71-76, and 78-84 to focus on SEQ ID NOs: 1463, 12600 (target protein) and 8502 (nucleic acid encoding target protein) related sequences. The related sequences are described in the claims by their relationship to SEQ ID NOs: 1463, 12600, or 8502. The amendment is without prejudice to future prosecution.

**35 U.S.C. § 112 (Written Description)**

Claims 31, 45-69, 71-84 and 101 stand objected to for allegedly failing to comply with the written description requirement. The examiner indicates that the central issue is that there is allegedly no direction or guidance provided in the specification for providing a sublethal level of an antisense nucleic acid having at least 97%, 95%, 90%, 85%, 80%, 70% sequence identity to SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation. The examiner also argues it would take undue experimentation to determine such antisense sequences.

Claim 31 is directed to a method for screening a candidate compound for the ability to reduce cellular proliferation involving the use of antisense nucleic acid targeting a gene product, where the claim lays out different descriptions of the gene product. The rejection is directed to the first description, which refers to percent identity to a reference sequence shown in the application to be able to reduce the activity of a gene product required for cellular proliferation.

The descriptions of percent sequence identity and antisense activity provides sufficient structural and functional characteristics to demonstrate applicants possessed the claimed subject matter. Percent identity provides an overall generic description based on a particular sequence that structurally distinguishes the nucleic acid from other nucleic acids.

Reference to antisense activity provides a functional description limiting the overall structure of the nucleic acid based on sufficient complementarity base pairing to have antisense activity. The specificity of complementarity binding between nucleic acid bases is well known in the art. (E.g., A-T, G-C base pair binding.)

The interim written description guidelines published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440 ("Guidelines"), cited by the examiner in the previous office action specifically notes:

An applicant may also show that an invention is complete by disclosure of sufficiently detailed **relevant identifying characteristics** which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or **partial structure**, other physical and/or chemical properties, **functional characteristics** when coupled with a known or disclosed correlation between function and structure, or some **combination of such characteristics**. [Emphasis added.]

Guidelines at page 71435, third column, second paragraph.

The examiner indicates it would take undue experimentation to determine appropriate antisense sequences. Determining what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test for undue experimentation is not merely quantitative. *Id.* A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Id.*

Based on the present application, it would not take undue experimentation to find appropriate antisense sequences to support the claims. As noted above, important structural and functional descriptions are provided. The skilled artisan need only perform routine testing of sequences within such descriptions (e.g., sequence of 70% identity) to confirm that such sequences have the desired antisense activity.

#### Double Patenting

Claims 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 stand rejected based on obviousness-type double patenting in view of claims 1-6, 9 and 10 of U.S. Patent No. 6,720,139 (the '139 patent). The Examiner argues that the '139 patent claims describe the different limitations of the rejected claims. The rejection is respectfully traversed.

The pending claims provide descriptions of sequences. The rejection fails to indicate where the '139 patent claims recite such sequences.

Accordingly the claims are in condition for allowance. Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

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